

# **EXHIBIT 4**

## **Appendix III.J: Framework for Estimating Harms Due to Distributor Misconduct**

1. As the Bellwether plaintiffs have alleged, the opioid epidemic and the need for increased services, “arose from the opioid manufacturers’ deliberately deceptive marketing strategy to expand opioid use, together with the distributors’ equally deliberate efforts to evade restrictions on opioid distribution.”<sup>1</sup> While the defendants’ misleading marketing contributed to the opioid epidemic, “the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies . . . who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls . . . thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.”<sup>2</sup>

2. Tables III.13 and III.14 report the share of harms due to defendants’ misconduct that are based on estimates of the share of prescription opioid shipments attributable to misleading marketing reported by Prof. Rosenthal. While this estimate may reflect the harm that could have been avoided in the absence of marketing misconduct, some portion of the harm resulting from such shipments also could have been avoided had CSA registrants, such as defendant distributors, not acted improperly. I understand that all CSA registrants such as distributors of prescription opioids have legal obligations to monitor, identify and report shipments to regulatory authorities that may be unrelated to medical need and to prevent such shipments. The alleged failure to carry out these responsibilities thus contributed to the explosion of prescription opioid shipments that contributed to the opioid crisis documented by Prof. Gruber.

3. The estimates of the share of harms due to defendants’ misconduct for Cuyahoga and Summit Counties reported in Tables III.16A-B do not attempt to uniquely attribute harm resulting from actions by any individual type of defendant. This does not reflect a problem with the underlying data or analysis but instead is the result of the fact that multiple parties are responsible for harms. For example, assume

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<sup>1</sup> Cuyahoga Complaint, ¶13; Summit Complaint ¶13.

<sup>2</sup> Cuyahoga Complaint, ¶14; Summit Complaint, ¶14.

that 80% of harm can be attributed to manufacturer misconduct and 70% of that harm could have been avoided if distributors had acted properly. As an economic matter, manufacturers are appropriately held liable for at least the 10% of the harm that distributors could not have avoided. However, as discussed in the report, there is no unique or economically “correct” allocation of liability for the 70% of harm that could have avoided if each party had it met its legal obligations. Note that it is not necessarily the case that harm due to misconduct by CSA registrants is a subset of harm due to misleading marketing. Even in the absence of improper marketing, the failure of distributors and other CSA registrants to identify suspicious and excessive shipments can result in harm.

4. Nonetheless, the share of harm for which distributors can potentially be said to be liable can be estimated based on a variant of the framework used in Section VII. Specifically, the share of harm potentially attributable to distributors can be calculated by applying an estimate of the *share of excessive shipments that distributors failed to identify* (to the extent such a measure is available) instead of the estimate of the *share of shipments due to misleading marketing misconduct* in the Section VII framework. More specifically, the share of harm attributable to distributor misconduct can be measured as:

$$\begin{aligned} & \text{Share of Harms Attributable to } \mathbf{Distributor} \text{ Misconduct} \\ &= \text{Share of Harms Attributable to Opioids} \\ & \quad \times \text{Share of Opioid Harms Attributable to Opioid Shipments} \\ & \quad \times \text{Share of Opioid Shipments Due to } \mathbf{Distributor} \text{ Misconduct} \end{aligned}$$

5. That is, modifying the Section VII framework to address distributor misconduct requires only a modification of the last input, the “*Share of Opioid Shipments Due to Distributor Misconduct*,” as the other two inputs are not specific to the attribution across the conduct of the multiple parties. This appendix presents an example of how this analysis can be applied if appropriate data become available

to estimate the share of prescription opioid shipments that reflect distributor misconduct. This example can be readily updated when appropriate estimates become available.

6. Table J.1 reports the data on the share of shipments for which the distributors are liable as described and set forth in the expert reports of Craig McCann and James Rafalski.<sup>3</sup>

**Table J.1: Percent of Shipments Attributable to Distributors' Misconduct**

<b>Year</b>	<b>Percent of Shipments Attributable to Distributors' Misconduct</b>
1997	41.4%
1998	56.3%
1999	56.4%
2000	51.8%
2001	54.2%
2002	51.0%
2003	57.9%
2004	56.1%
2005	57.1%
2006	64.4%
2007	73.6%
2008	76.2%
2009	72.4%
2010	74.8%
2011	78.3%
2012	79.5%
2013	69.6%
2014	76.3%
2015	82.9%
2016	80.6%

These shares provide estimates of shipments of prescription opioids that would have been avoided in the absence of distributors' misconduct and can be used to estimate average shipments but-for

<sup>3</sup> Supplemental Expert Report of Craig J. McCann, Ph.D., CFA, April 3, 2019, Table A; James A. Rafalski, Expert Report: Analysis of Distributor and Manufacturer Regulatory Compliance to Maintain Effective Controls for the Prevention of Diversion of Controlled Substances, April 15, 2019, Section III.

distributor misconduct. Incorporating these estimates into the Approach 1 and Approach 2 analyses (discussed in Section VI) then yields an estimate of the share of harms attributable to distributors' misconduct. Specifically, the calculation yields estimate of the product of the "*Share of Opioid Harms Attributable to Opioid Shipments*" and "*Share of Opioid Shipments Due to Distributor Misconduct*" in the equation above. Tables J.2 and J.3 below present these results.

**Table J.2: Percent of Harms Attributable to Distributors' Misconduct Under Approach 1  
2006 – 2016**

Year	Any Opioid			Licit (Rx + Methadone)			Illicit (Heroin + Fentanyl)			Total			
	Actual Mortality	Impact on Mortality	But-For Mortality	Actual Mortality	Impact on Mortality	But-For Mortality	Actual Mortality	Impact on Mortality	But-For Mortality	Actual Mortality	Impact on Mortality	But-For Mortality	Percent Impact
	A	B	C = A - B	D	E	F = D - E	G	H	I = G - H	J	K	L = J - K	M = K / J
2006	9.97	2.76	7.21							9.97	2.76	7.21	27.7%
2007	10.51	3.12	7.39							10.51	3.12	7.39	29.7%
2008	11.06	3.47	7.59							11.06	3.47	7.59	31.4%
2009	11.45	3.77	7.68							11.45	3.77	7.68	32.9%
2010	11.66	4.09	7.57							11.66	4.09	7.57	35.1%
2011				8.23	2.97	5.27	3.80	1.61	2.19	12.03	4.58	7.45	38.1%
2012				7.47	3.15	4.32	4.55	2.25	2.30	12.02	5.40	6.62	44.9%
2013				6.92	3.26	3.66	5.65	3.08	2.57	12.57	6.34	6.23	50.5%
2014				6.57	3.37	3.19	7.28	4.33	2.95	13.85	7.70	6.14	55.6%
2015				6.05	3.49	2.56	9.22	5.81	3.41	15.27	9.30	5.97	60.9%
2016				5.91	3.56	2.35	12.20	8.00	4.20	18.11	11.56	6.55	63.8%

**Table J.3: Percent of Harms Attributable to Distributors' Misconduct Under Approach 2  
2006 – 2016**

Year	Actual Mortality	Predicted Mortality	Percent Impact of All Shipments	Weighted Average Cumulative Percent of Shipments Attributable to Defendants' Misconduct	Percent Impact
				D	
	A	B	C = (A - B) / A		E = C * D
2006	8.46	1.38	83.7%	56.2%	47.1%
2007	9.13	1.31	85.6%	59.0%	50.5%
2008	9.83	1.45	85.2%	61.4%	52.3%
2009	9.69	2.22	77.1%	62.8%	48.5%
2010	10.23	2.27	77.8%	64.3%	50.0%
2011	11.44	2.04	82.2%	65.9%	54.2%
2012	11.62	1.85	84.1%	67.3%	56.6%
2013	12.31	1.73	85.9%	67.5%	58.0%
2014	13.75	1.51	89.0%	68.2%	60.7%
2015	15.39	1.38	91.1%	69.2%	63.0%
2016	18.46	1.33	92.8%	69.9%	64.9%

7. The final step in the estimation is to combine these estimates with the “Share of Harm Attributable to Opioids” for the divisions identified in Cuyahoga and Summit counties, as described in Section IV. Tables J.4 and J.5 below report these results.

**Table J.4: Share of Cuyahoga Opioid Harms Due to Distributors’ Misconduct**

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
<b>Approach 1</b>													
ADAMHS Board	0.9%	1.1%	1.4%	1.4%	1.5%	1.6%	1.8%	3.5%	4.0%	5.4%	7.8%	8.9%	8.9%
DCFS	1.3%	1.6%	1.9%	2.3%	2.6%	2.8%	3.3%	4.5%	5.6%	6.7%	9.5%	10.0%	10.0%
Office of Prosecutor	1.5%	1.6%	2.3%	2.8%	3.4%	3.7%	4.4%	5.1%	5.2%	5.3%	5.8%	7.0%	7.0%
Office of Public Defender	1.5%	1.6%	2.3%	2.8%	3.4%	3.7%	4.4%	5.1%	5.2%	5.3%	5.8%	7.0%	7.0%
Court of Common Pleas	1.6%	1.7%	2.3%	2.8%	3.5%	3.8%	4.6%	5.5%	5.8%	5.9%	6.4%	7.8%	7.8%
Juvenile Court	0.5%	0.5%	0.7%	0.8%	0.8%	0.9%	1.0%	1.4%	1.9%	1.9%	2.8%	2.8%	2.8%
Sheriff's Office	1.5%	1.6%	2.3%	2.8%	3.4%	3.7%	4.4%	5.1%	5.2%	5.3%	5.8%	7.0%	7.0%
County Jail	1.5%	1.6%	2.3%	2.8%	3.4%	3.7%	4.4%	5.1%	5.2%	5.3%	5.8%	7.0%	7.0%
Office of Medical Examiner	2.5%	2.5%	3.8%	4.9%	6.0%	8.1%	9.7%	12.5%	13.6%	14.3%	24.2%	24.5%	24.5%
<b>Approach 2</b>													
ADAMHS Board	1.5%	2.0%	2.3%	2.1%	2.2%	2.2%	2.3%	4.0%	4.4%	5.5%	7.9%	9.1%	9.1%
DCFS	2.1%	2.7%	3.2%	3.4%	3.7%	4.0%	4.1%	5.1%	6.1%	6.9%	9.7%	10.2%	10.2%
Office of Prosecutor	2.6%	2.8%	3.8%	4.1%	4.8%	5.2%	5.6%	5.8%	5.7%	5.5%	5.9%	7.1%	7.1%
Office of Public Defender	2.6%	2.8%	3.8%	4.1%	4.8%	5.2%	5.6%	5.8%	5.7%	5.5%	5.9%	7.1%	7.1%
Court of Common Pleas	2.7%	2.8%	3.8%	4.2%	4.9%	5.4%	5.8%	6.3%	6.3%	6.1%	6.5%	7.9%	7.9%
Juvenile Court	0.8%	0.9%	1.2%	1.1%	1.2%	1.3%	1.3%	1.6%	2.0%	2.0%	2.8%	2.8%	2.8%
Sheriff's Office	2.6%	2.8%	3.8%	4.1%	4.8%	5.2%	5.6%	5.8%	5.7%	5.5%	5.9%	7.1%	7.1%
County Jail	2.6%	2.8%	3.8%	4.1%	4.8%	5.2%	5.6%	5.8%	5.7%	5.5%	5.9%	7.1%	7.1%
Office of Medical Examiner	4.3%	4.3%	6.3%	7.2%	8.6%	11.5%	12.2%	14.4%	14.8%	14.8%	24.6%	24.9%	24.9%

**Table J.5: Share of Summit Opioid Harms Due to Distributors’ Misconduct**

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
<b>Approach 1</b>													
ADM Board	0.5%	0.6%	0.7%	0.9%	2.1%	2.1%	3.7%	6.1%	7.0%	8.0%	9.8%	8.8%	8.8%
Children Services Board	1.2%	1.5%	2.0%	2.9%	7.7%	8.1%	10.5%	12.4%	13.4%	15.2%	19.4%	17.2%	17.2%
Prosecutor	1.5%	1.5%	2.1%	2.6%	2.8%	3.4%	4.3%	4.7%	5.6%	7.0%	7.6%	7.5%	7.5%
Court of Common Pleas	1.5%	1.5%	2.1%	2.6%	2.8%	3.4%	4.3%	4.7%	5.6%	7.0%	7.6%	7.5%	7.5%
Juvenile Court	0.7%	0.8%	1.1%	1.3%	1.6%	1.9%	2.4%	2.5%	2.9%	3.4%	4.3%	4.2%	4.2%
Sheriff's Office	1.5%	1.5%	2.1%	2.6%	2.8%	3.4%	4.3%	4.7%	5.6%	7.0%	7.6%	7.5%	7.5%
County Jail	1.5%	1.6%	2.2%	2.6%	3.1%	3.3%	3.9%	4.5%	5.1%	5.7%	6.0%	6.0%	6.0%
Alternative Corrections	1.5%	1.6%	2.2%	2.6%	3.1%	3.3%	3.9%	4.5%	5.1%	5.7%	6.0%	6.0%	6.0%
Adult Probation	1.5%	1.5%	2.1%	2.6%	2.8%	3.4%	4.3%	4.7%	5.6%	7.0%	7.6%	7.5%	7.5%
Medical Examiner	3.0%	3.1%	3.0%	4.4%	5.4%	4.8%	7.9%	7.8%	13.0%	16.4%	23.6%	20.4%	20.4%
<b>Approach 2</b>													
ADM Board	0.8%	1.0%	1.2%	1.4%	2.9%	3.0%	4.6%	7.0%	7.7%	8.3%	9.9%	8.9%	8.9%
Children Services Board	2.0%	2.6%	3.4%	4.3%	11.0%	11.5%	13.2%	14.3%	14.6%	15.8%	19.7%	17.5%	17.5%
Prosecutor	2.5%	2.5%	3.4%	3.9%	4.0%	4.9%	5.4%	5.4%	6.1%	7.2%	7.7%	7.7%	7.7%
Court of Common Pleas	2.5%	2.5%	3.4%	3.9%	4.0%	4.9%	5.4%	5.4%	6.1%	7.2%	7.7%	7.7%	7.7%
Juvenile Court	1.2%	1.4%	1.8%	1.9%	2.2%	2.7%	3.0%	2.9%	3.2%	3.5%	4.4%	4.2%	4.2%
Sheriff's Office	2.5%	2.5%	3.4%	3.9%	4.0%	4.9%	5.4%	5.4%	6.1%	7.2%	7.7%	7.7%	7.7%
County Jail	2.6%	2.7%	3.6%	3.8%	4.4%	4.7%	4.9%	5.2%	5.5%	5.9%	6.1%	6.1%	6.1%
Alternative Corrections	2.6%	2.7%	3.6%	3.8%	4.4%	4.7%	4.9%	5.2%	5.5%	5.9%	6.1%	6.1%	6.1%
Adult Probation	2.5%	2.5%	3.4%	3.9%	4.0%	4.9%	5.4%	5.4%	6.1%	7.2%	7.7%	7.7%	7.7%
Medical Examiner	5.2%	5.3%	5.0%	6.5%	7.7%	6.8%	10.0%	9.0%	14.1%	17.0%	24.0%	20.7%	20.7%